Executive Summary

The goal of the Mammography Quality Standards Act (MQSA) of 1992, as amended by the Mammography Quality Standards Reauthorization Act (MQSRA) of 2004, is to ensure that facilities meet standards for performing high quality mammography. The Food and Drug Administration (FDA) administers MQSA. Among other things, MQSA provides for the FDA-approved accreditation bodies (ABs) to evaluate and accredit mammography facilities against quality standards. Based on successful completion of this process, FDA then issues certificates to the facilities so that they can legally operate. MQSA requires annual reports to Congress on AB performance. This ninth annual report covers the period from January 1 through December 31, 2004.

To implement the MQSA (Public Health Service Act section 354, 42 USC section 263b), FDA issued final regulations that became effective on April 28, 1999 (21 CFR Part 900). The final regulations state that FDA's evaluation of ABs shall include a(n):

(a) Assessment of the reports of FDA or state inspections of facilities accredited by the body as well as any additional information deemed relevant by the FDA that has been provided by the accreditation body or other sources or has been required by the FDA as part of its oversight initiatives;

(b) Determination of whether there are major deficiencies in the AB's performance that, if not corrected, would warrant withdrawal of the approval of the AB under the provisions of Section 900.6.

Status of Accreditation Bodies

FDA approved the American College of Radiology (ACR), a private, nonprofit organization, as well as the states of Arkansas, Iowa, and Texas under the MQSA and the final regulations. Since each AB's approval expires on April 28, 2006, they will begin the renewal process in the fall of 2005.

FDA approved the State of California (SCA) under the interim MQSA regulations in 1994. Then, in 1998, the SCA applied for AB status under the final regulations. Despite the collaborative efforts of FDA and the SCA, the State was unable to develop its MQSA accreditation program to achieve approval under the final regulations. Therefore, on May 5, 2004, the SCA withdrew its application to become an FDA-approved AB under the MQSA final regulations. Through its withdrawal, the SCA relinquished its authority and responsibilities under the MQSA. Section 900.13(b)(1) and (2) (under 21 CFR Part 900) allows certificates of facilities previously accredited by a withdrawn AB to remain in effect for up to one year from the date of the withdrawal of approval, unless FDA determines that there are public health issues or that the AB fraudulently accredited any of its facilities. As a result of the SCA's withdrawal, all SCA-accredited facilities were required to apply for accreditation from the ACR no later than May 5, 2005. On May 7, 2004, and May 13, 2004, the SCA and the FDA, respectively, notified all SCA-accredited

facilities (465) of the State's withdrawal and the MQSA requirement that these facilities obtain accreditation from the ACR within one-year. As of May 5, 2005, all SCA facilities had transitioned to the ACR.

Core Functions of the Accreditation Bodies

The ABs review documentation and clinical[1] and phantom[2] images that are submitted by mammography facilities for accreditation purposes. On determining that facilities meet specific requirements, the ABs make a positive accreditation decision. FDA then certifies the facilities based on that accreditation.

FDA evaluates the ABs on a number of elements, but concentrates on these core AB functions:

- Clinical Image Review
- Phantom Image Review
- Random Clinical Image Review
- Onsite Visits
- Equipment Requirements
- Consumer Complaint Mechanism
- Additional Mammography Review

Performance Indicators

FDA evaluates the performance of its ABs through:

- examination of their responses to FDA questionnaires that address performance indicators;
- analysis of quantitative accreditation and inspection information;
- review of selected files, as well as clinical and phantom images;
- interviews with staff and management to answer questions or clarify issues;
- analysis of information from its Mammography Program Reporting and Information System; and
- on-site visits

To assess overall performance of the ABs, the agency evaluates information in various areas: administrative processes, reporting and record keeping processes, accreditation review and decision-making processes, AB on-site visits to facilities, random clinical image reviews, additional mammography reviews, and accreditation revocations and suspensions. FDA's evaluation includes on-site visits to the ABs and ongoing written and oral communications with the ABs.

[1] Clinical image review: the facility must submit to the AB two cases (one fatty breast and one dense breast) to be reviewed and scored by an AB panel of trained interpreting physicians. Each case consists of four views, two craniocaudal and two mediolateral oblique views.

[2] Phantom images are x-ray films of plastic objects that contain various simulated abnormalities of breast tissues. Phantom images are used to test the ability of the equipment to discriminate abnormalities.

Findings from CY 2004 AB Performance Evaluations

The following items are highlights of FDA's CY 2004 report to Congress:

- All ABs adequately fund their respective programs.
- All ABs took appropriate measures to secure and maintain their accreditation data, although data errors increased slightly.
- Each AB has a satisfactory serious consumer complaint process.
- Each AB used acceptable procedures to review clinical images submitted by facilities, and has adequate audit procedures for its clinical image reviewers.
- Each AB used acceptable procedures to review phantom images submitted by facilities, and has adequate audit procedures for its phantom image reviewers.
- All ABs met or exceeded the required number of AB on-site visits to facilities they accredit.
- All ABs exceeded the required number of random clinical image reviews of the facilities they accredit.
- The ABs performed additional mammography reviews when indicated.
- One AB revoked the accreditation of two of its facilities and one AB suspended the accreditation of one of its facilities in CY 2004.
- Facilities' phantom image scores showed no significant differences across the ABs. Phantom image scores improved slightly from those reported in the 2003 report.
- Overall, the rates for units that failed accreditation increased slightly (0.8 percent) from those in the last reporting period.
- Generally, the average radiation doses measured at the facilities of all the ABs decreased slightly from those in the previous report and remain well below the dose limit mandated by the MQSA final regulations.
- In CY 2004, over half (68.8 percent) of the accredited mammography facilities received no violations during their MQSA inspection, while only 2.1 percent of facilities had a violation characterized as "most serious." FDA actively works with these facilities on corrective measures, and takes regulatory actions as indicated.
- On May 5, 2004, the State of California withdrew its application to become an FDA-approved AB under the MQSA final regulations.
- As of May 5, 2005, all SCA facilities had transitioned to the ACR.
- There were no action items in the AB's CY 2004 Performance Evaluations.

FDA and the ABs, working in partnership with the certified mammography facilities in the United States, as well as the states participating in inspections and other MQSA activities, are ensuring quality mammography across the Nation.